Services Agreement

Trials@Home
Center of Excellence
Remote Decentralised Clinical Trials

Between

Legal Name Vendor
Address
Zip Code, Place
Country

And

Julius Clinical
a registered trade name of
Julius Clinical research B.V.
Broederplein 41-43
3703 CD Zeist
The Netherlands

All documents issued by the vendor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in this agreement. In all circumstances, in the event of contradiction between this agreement and documents issued by the vendor, this agreement prevails, regardless of any provision to the contrary in the vendor's documents.

Services Agreement

This services agreement (hereinafter referred to as "**Agreement**") is made and entered into as of the Month Day, Year (hereinafter referred to as "**Effective Date**") by and between

Julius Clinical, *a registered trade name of Julius Clinical Research B.V.,* a limited liability company, incorporated and operating under the laws of the Netherlands, having its registered and principal office at Broederplein 41-43, 3703 CD Zeist, the Netherlands, with VAT number NL 8197.31.547 B01 and registered at the Chamber of Commerce under number 30244124, hereinafter referred to as "**Julius Clinical**".

and

Legal Name Vendor, a limited liability company, incorporated and operating under the laws of Country, having its registered and principal office at Street, Zip code, Place, Country, with VAT/tax identity number VAT Number OPTION and registered at the Chamber of Commerce under number Number, hereinafter referred to as "**Vendor**".

Vendor and/or Julius Clinical may also hereinafter be referred to individually as "**Party**" or collectively as "**Parties**".

WHEREAS further to a multi-beneficiary funding award by the Innovative Medicines Initiative 2 Joint Undertaking programme ("**IMI**") for the action "Trials@Home: Center of Excellence – Remote Decentralised Clinical Trials" ("**Action**"), a consortium has been formed by certain beneficiaries and a grant agreement has been signed between those beneficiaries (each a "**Beneficiary**" and collectively "**Beneficiaries**") and IMI ("**Grant Agreement**"), to which Universitair Medisch Centrum Utrecht ("**Sponsor**") and Julius Clinical are parties;

WHEREAS further to the Grant Agreement; (a) Sponsor is the coordinator of the Action and sponsor of the pan European clinical study pilot ("**Study**") undertaken as part of the Action; (b) Julius Clinical is a science driven Contract Research Organization, acting as an independent contractor of Sponsor and Sponsor has delegated some of Sponsor's responsibilities with respect to the Study to Julius Clinical;

WHEREAS Julius Clinical, acting as an independent contractor of Sponsor, would like to retain certain services of Vendor for the Study and Vendor desires to supply such services.

NOW THEREFORE, in consideration of the mutual covenants and undertakings herein contained, the Parties, intending to be legally bound, hereby agree as follows:

1. SCOPE OF AGREEMENT

1.1 Services. The services to be performed by Vendor to Julius Clinical under this Agreement are described in detail in Attachment A (hereinafter referred to as "**Services**"). Julius Clinical may request a change in the scope of the Services which will be agreed between the Parties in writing. Parties shall enter in good faith discussions to accommodate such changes.

1.2 Special conditions. Special conditions may apply to certain Services as included in [Attachment D]. In the event of a conflict between these special conditions and the terms and conditions of the main body of the Agreement, the Agreement's main body prevails, unless explicitly set forth otherwise in the respective special conditions.

1.3 Service standards. Vendor will perform the Services in accordance with this Agreement, all applicable laws, regulations and good practices, including but not limited to the applicable personal data protection legislation, the relevant protocol, Sponsor's and Julius Clinical's instructions and all applicable professional and ethical standards generally accepted in the clinical trial industry.

1.4 Grant Agreement. To the extent applicable, the articles of Attachment C, which flow down from the Grant Agreement, apply *mutatis mutandis* to the Vendor. In the event of a conflict between the articles of Attachment C and the terms and conditions of the Agreement (including the other Attachments of the Agreement), Attachment C prevails.

1.5 Data Processing Agreement. Parties shall separately conclude a data processing agreement to regulate the terms and conditions of any personal data processed by Vendor pursuant to this Agreement.

2. PAYMENT OF PROFESSIONAL FEES AND EXPENSES

2.1 Professional Fees. In consideration of the Services performed, Julius Clinical shall pay Vendor the compensation as specified in Attachment B ("**Professional Fees**"), in accordance with the terms of this Agreement. The Professional Fees are not subject to price revisions.

2.2 Expenses. Julius Clinical shall reimburse Vendor for travel and other reasonable out-of-pocket expenses incurred by Vendor staff in the performance of the Services as specified in Attachment B ("**Expenses**"). Julius Clinical shall reimburse only such Expenses which have been pre-approved in writing by Julius Clinical. Vendor will submit adequate documentation of such Expenses.

2.3 Payment Term. Invoices will be provided by Vendor to Julius Clinical on a monthly basis and will identify work performed for the invoiced month. Julius Clinical shall pay any undisputed invoice within forty-five (45) days of invoice date. If any portion of the invoice is disputed, then Julius Clinical shall notify Vendor within fourteen (14) days of invoice date and pay the undisputed amounts as set forth above. Parties shall use good faith efforts to reconcile the disputed amount

within thirty (30) days after the notification of Julius Clinical in accordance with the provisions of this Article 2.3.

2.4 Payment Schedule. Vendor shall invoice the Professional Fees and Expenses in accordance with the schedule set forth in Attachment B.

2.5 Currency. All amounts are calculated and paid in Euro (€). All Expenses incurred in a different currency shall be converted into Euro (€) amounts using the OANDA daily rate (http://www.oanda.com/currency/converter/) of the date of invoice by the concerning third party as specified on the concerning invoice provided to Julius Clinical.

2.6 Taxes. Payments under this Agreement include any taxes, social insurance, other premiums or contributions that Vendor is legally or contractually obligated to pay and Vendor shall be solely liable for payment of such costs.

3. CONFIDENTIALITY

3.1 Confidential Information. For the purposes of this Agreement, "**Confidential Information**" shall mean any and all data, information, documents or other material (in any form), irrespective of its form (i) received or obtained by Vendor from Julius Clinical or Sponsor or otherwise made accessible to Vendor by Julius Clinical or Sponsor (prior to or after the signature of this Agreement) whether directly or indirectly; and/or (ii) created by Vendor as a result of the performance of the Services under the Agreement, which if disclosed, could be harmful to Julius Clinical and/or a Beneficiary. Confidential Information shall further include the existence and content of this Agreement.

3.2 Obligations. During the term of this Agreement and for an additional period of ten (10) years following the expiration or termination of this Agreement or for any longer period as may be required by mandatory applicable law, Vendor shall:

(a) hold in strict confidence the Confidential Information and use the Confidential Information only for the purpose of performing the Services pursuant to this Agreement, and

(b) protect Confidential Information against unauthorized disclosure and access and to ensure the secured storage of any Confidential Information, whether in hard copy or electronically, and

(c) not use the Confidential Information to the detriment of Julius Clinical and/or Sponsor nor to compete with Julius Clinical or use it for any other purpose than performing its obligations or exercising its rights under this Agreement, without the prior written approval of Julius Clinical, and

(d) not reveal, publish or otherwise disclose any of the Confidential Information, in whole or in part, to any person or entity other than its own employees and consultants who have a need to know such Confidential Information and provided that Vendor has contractually bound the concerning employees or consultants by confidentiality, non-disclosure and non-use obligations equivalent to those contained in this Agreement.

(e) to notify promptly Julius Clinical management should any unauthorized disclosure of Confidential Information occur.

3.3 Exceptions. The obligations under Articles 3.2 shall not apply to Confidential Information to the extent that is clearly and convincingly shown, that such information:

(a) is or becomes generally available to the public other than as a result of a disclosure by the Vendor, and/or

(b) becomes available to the Vendor on a non-confidential basis from a source (other than Julius Clinical or Sponsor) which is not prohibited from disclosing the information, and/or

(c) was independently developed by the Vendor without the use of Confidential Information, as shown by contemporaneous evidence, and/or

(d) was in the Vendor's possession prior to receipt from Julius Clinical and/or Sponsor and which had not previously been obtained from Julius Clinical and/or Sponsor or any other party under an obligation of confidence; and/or

(e) is required by law to be disclosed, provided that Vendor immediately notifies Julius Clinical in writing of such requirement (to the extent permitted by law) and only discloses the information to the extent so required to be disclosed. Such disclosure shall not release the Confidential Information from its confidential status.

3.4 Ownership. Without prejudice to Article 4 below, all Confidential Information will remain the sole and exclusive property of Julius Clinical, Sponsor or any of the Beneficiaries, as applicable.

3.5 Vendor's confidential information. Julius Clinical will comply with nondisclosure obligations in accordance with articles 3.2 and 3.3 of this Agreement with respect to information that it receives from Vendor and which is marked "confidential", with the exception of information which Vendor explicitly or implicitly discloses to Julius Clinical for the purpose of being forwarded by Julius Clinical to one or several of Julius Clinical's clients, prospective clients or a Beneficiary.

3.6 Transfer of Documents. Each Party shall upon termination or expiration of this Agreement or upon request of the disclosing Party promptly transfer to the other Party all documents containing confidential information which by virtue of this Agreement is the property of the other Party, except for one archival copy in a secure place for reference and proof. The provisions of this article shall not apply to copies of electronically exchanged confidential information made as a matter of routine information technology backup and to confidential information or copies thereof which must be stored by the receiving Party according to provisions of mandatory law.

4. INTELLECTUAL PROPERTY

4.1 Julius Clinical Rights. All data and information generated or derived by Vendor as the result of Services performed by Vendor and/or its staff under this Agreement or through the use of or access to the Confidential Information shall be and remain the exclusive property of Julius Clinical, Sponsor and/or any Beneficiary, as applicable. All data, information, reports, and any discoveries,

inventions, works of authorship, ideas, suggestions that may evolve from the data and information described above or as the result of Services performed by Vendor under this Agreement or through the use of or access to the Confidential Information (collectively "**Developments**") shall belong to Julius Clinical, Sponsor and/or a Beneficiary, as applicable, and Vendor agrees and shall cause its staff, to promptly inform Julius Clinical of such Developments, and hereby fully assigns to Julius Clinical, Sponsor and/or the relevant Beneficiary all of its rights in all such Developments and any related patents, copyrights and other intellectual property rights.

4.2 Vendor obligations. Vendor shall ensure that any documents are executed and acts are performed by Vendor and/or its staff as are necessary for the assignment of the property of such Developments to Julius Clinical, Sponsor and/or the relevant Beneficiary, as applicable. Parties agree that the amounts due by Julius Clinical under the Agreement for the conduct of the Services by Vendor constitute full and sufficient consideration for the creation, development, conception or reduction to practice of any Developments by Vendor, and/or its staff. Therefore, neither Julius Clinical, Sponsor nor the relevant Beneficiary is liable for any additional payments to Vendor for Developments by Vendor, and/or its staff, their coming into existence. Any and all Developments shall be considered to be Confidential Information under this Agreement.

4.3 Vendor Rights. Without prejudice to the above, Julius Clinical acknowledges that Vendor possesses or may in the future possess certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, which have been independently developed by Vendor and which relate to the business or operations of Vendor and are not based on any Confidential Information or Developments (collectively "**Vendor's Property**"). Notwithstanding the above, Julius Clinical, Sponsor and the relevant Beneficiary shall have a non-exclusive, irrevocable, perpetual, worldwide, royalty-free license to use Vendor's Property in conjunction with the Development and Confidential Information and the commercial use by Julius Clinical, Sponsor, and the relevant Beneficiary and/or their respective affiliates of the subject matter of this Agreement and the Protocol, and with the right to sub-license.

5. TERM, TERMINATION AND SUSPENSION

5.1 Term. This Agreement shall be effective as of the Effective Date and expire upon completion or termination of the Study, termination of participation of Julius Clinical in the Action or early termination of the Consortium Agreement or Grant Agreement, whichever occurs sooner.

5.2 Early Termination by Either Party. Julius Clinical may terminate this Agreement at any time by giving a thirty (30) days written notice.

5.3 Payment upon Termination. Upon termination of this Agreement Julius Clinical shall pay any outstanding Professional Fees under this Agreement for the Services actually completed in accordance with the terms of this Agreement by Vendor up to the effective date of the termination.

Vendor shall promptly refund any payments made in advance by Julius Clinical to Vendor for work not completed or that are not due under the Agreement.

5.4 Suspension. Should the Action be suspended in accordance with the Grant Agreement, Julius Clinical reserves the right to suspend this Agreement. For the avoidance of any doubt no payments will be made by Julius Clinical during the period of the suspension.

5.5 Survival of terms. The rights and obligations of the Parties under Articles 2.3 (payment term), 3 (confidentiality), 4 (intellectual property), 5.3 (payment upon termination), 5.5 (survival of terms), 6 (indemnification), 7 (limitation of liability), 9 (notices), 10 (audits and inspections), 11.5 (assignment), 11.6 (waiver), 11.7 (severability), 11.8 (entire agreement and modification), 11.9 (law and jurisdiction) of this Agreement and Attachment C shall survive termination or expiration of this Agreement.

6. INDEMNIFICATION

Vendor hereby agrees to indemnify, defend, and hold Julius Clinical, its employees, directors, officers, contractors and agents harmless from any and all third party claims or demands for damages, liabilities, losses, actions and/or suits, including reasonable attorney's fees and court or arbitration costs (hereinafter referred to as "**Third Party Claims**") arising directly as a result of Vendor's negligence or intentional misconduct in the performance of its obligations under this Agreement or Vendor's breach of any data processing agreement agreed between the Parties, except to the extent that any such Third Party Claims are directly caused by Julius Clinical's negligence or intentional misconduct.

7. LIMITATION OF LIABILITY

Parties agree that, in the event of any breach or default by either Party with respect to this Agreement, the defaulting Party's damage liability to the non-defaulting Party for such breach or default (whether in tort, contract, strict liability or otherwise) shall be limited to the non-defaulting Party's direct damages. Under no circumstances shall either Party be liable towards the other Party for any form of consequential, special, punitive or indirect damages (to include loss of profit or business) for the breach of its obligations under this Agreement.

8. WARRANTIES

8.1 Warranties. Vendor warrants that:

(a) it has, or will have before doing so, all necessary authorisations to enter into and perform the Agreement; and

(b) it has sufficient, staff, equipment, facilities and resources to perform the Services in accordance with the Agreement; and

(c) its staff are sufficiently qualified, trained and experienced; and

(d) its staff are not debarred, disqualified, blacklisted or banned under any applicable law or regulation or otherwise prohibited by relevant authorities from performing the Services, nor are currently to the best of Vendor's knowledge, the subject of such debarment, disqualification, blacklisting or banning proceeding and that it will notify Julius Clinical

immediately after being informed of any debarment, disqualification, blacklisting or banning action, or investigation with regard to such, against any member of its staff; and

(e) in case of any failure to comply with Julius Clinical's and/or Sponsor's instructions, or Study protocol requirements, Vendor shall immediately inform Julius Clinical by telephone or fax, providing in addition any supplementary information available to Vendor. Julius Clinical s approval shall be required ahead of further processing; and

(f) the use by Julius Clinical of any software, documents, information or any other materials provided or made accessible by Vendor to Julius Clinical pursuant to this Agreement, does not infringe any third party rights, including but not limited to intellectual property rights.

9. NOTICES

Any notice, consent, request or other communication required or permitted hereunder shall be made in writing and shall be deemed given if

(a) delivered personally, on the date received, or

(b) by a reputable overnight delivery service, on the next business day after being placed in the possession of such service, or

(c) by facsimile or e-mail, when electronic confirmation of receipt is received, or

(d) by mail, three days after the date postmarked if sent by registered or certified mail, return receipt requested, postage paid, to the address specified in the Parties section above and to the attention of the person that has signed this Agreement on behalf of the addressed Party.

10. AUDITS AND INSPECTIONS

10.1 Audits. Upon reasonable notice, Vendor shall allow Julius Clinical, Sponsor and their authorized representatives to examine and audit Vendor's facilities, equipment, documents and records relating to the Services, this Agreement and the relevant Work Order, for the purpose of and to the extent reasonably necessary for determining Vendor's compliance with the terms of this Agreement. Vendor and Julius Clinical shall agree on appropriate measures to prevent the unconsented processing of personal data and the breach of any confidentiality and non-disclosure obligations which Vendor may have towards third parties in respect of information unrelated to the Services.

10.2 Inspections. To the extent allowed by law, each Party shall:

(a) notify the other Party by telephone, facsimile or e-mail with electronic confirmation of receipt, immediately after being informed of any inspection relating to the Services, this Agreement or the relevant Work Order and to be conducted by a governmental or other competent or purportedly competent authority; and

(b) allow the other Party and its authorized representatives to be present and to participate in the inspection; and

(c) provide the other Party promptly with copies of any correspondence or other documents related to such inspection.

11. MISCELLANEOUS

11.1 Third Party Beneficiary. The Vendor agrees that Sponsor is a direct beneficiary of the rights attributed to it by virtue of this Agreement and may, unless this would contradict explicit instructions of Julius Clinical, enforce its rights hereunder as a third party beneficiary. In the event that Sponsor is not able to do so for any reason, the Vendor agrees that Julius Clinical may have the benefit of Sponsor's rights hereunder (including those rights concerning Confidentiality and Intellectual Property) and may transfer such rights and benefits to Sponsor. The Vendor furthermore agrees that IMI, the European Commission, the European Court of Auditors and the European Anti-Fraud Office are direct beneficiaries of the rights attributed to it by virtue of articles 22 and 23 as laid down in Attachment C of this Agreement.

11.2 Insurance. Each Party will maintain insurance, with a financially sound and reputable insurer, in an amount that will be adequate to cover its obligations under this Agreement, and, upon request each Party shall provide to the other Party a certificate of insurance showing that such insurance is in place. Parties ensure that insurance premiums are duly paid in order to avoid any suspensions of the concerning insurance policies.

11.3 Independent Contractor Relationship. The Parties are independent entities engaged in independent businesses, and no Party shall be regarded as, act as or purport to be an agent or employee of the other Party. Nothing herein shall be construed as:

(a) reserving for a Party the right to control the other Party in the management of its employees or conduct of its business and/or;

(b) granting either Party the authority to make any promise, guarantee, warranty, representation, contract or commitment which would create any obligation or liability whatsoever, whether express or implied, on behalf of the other Party; and/or

(c) creating a partnership, joint venture, principal and agent relationship or employer-employee relationship.

11.4 Force Majeure. Neither Party shall be liable for the delay in performance or failure to perform this Agreement if such delay or failure is due to any occurrence which was not reasonably foreseeable to the respective Party at or before the date of execution of this Agreement and which is beyond the control of the respective Party such as fire, explosion, weather, pandemic, disease, war, insurrection, civil strife, riots, government action or power failure; provided, however, that the Party who is unable to perform resumes performance as soon as possible following the end of the occurrence causing delay or failure.

11.5 Assignment. Vendor shall not assign, delegate, subcontract or transfer any of its rights, obligations or performance under the Agreement ("**Assignment**") without Julius Clinical's explicit prior written consent. Any purported assignment or delegation in violation of the foregoing sentence is void. In the event of Assignment, Vendor shall remain responsible for full performance of this Agreement.

11.6 Waiver. The waiver of either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppel with respect to any subsequent breach or with respect to any provision of this Agreement.

11.7 Severability. If any provision of this Agreement is found by a court of competent jurisdiction to be unenforceable, that provision will be severed and the remainder of this Agreement will continue in full force and effect. Any such provision shall be deemed to be replaced by a provision which, while in accordance with the applicable law, reflects the original provision as much as possible.

11.8 Entire Agreement and Modification. This Agreement shall enure to the benefit of and be binding upon the Parties and their respective successors and permitted assigns. This Agreement, including the Preamble, Recitals and any attachments, amendments, if any, hereto, constitutes the entire agreement between the Parties and supersedes all prior oral or written agreements or understandings with respect to the subject matter of this Agreement. Any modifications to the provisions herein must be in writing and signed by the legally authorized representatives of the Parties.

11.9 Law and Jurisdiction. This Agreement will be governed by and construed in accordance with the laws of the Netherlands, without its conflict of laws provisions. In the event of any dispute between the Parties in respect of or in connection with this Agreement, Parties shall first endeavour to resolve it amicably. Should Parties fail to reach and amicable settlement, any such dispute between the Parties will be submitted to the competent courts of, Utrecht the Netherlands.

In witness whereof, the Parties hereto have caused this Agreement to be executed in two or more counterparts by their duly legally authorized representatives. Parties acknowledge and agree that each has read the Agreement and agrees to be bound by the terms and conditions hereof.

Legal Name Vendor		**Julius Clinical**	
Name		Name	Aize Smink
Title		Title	CEO
Place, Country		Place, Country	Zeist, The Netherlands
Date		Date	

ATTACHMENT A

[Description of Services]

ATTACHMENT B

[Professional Fees and Expenses]

ATTACHMENT C

Relevant clauses from the Grant Agreement

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the JU and the Commission

22.1.1 Right to carry out checks

The JU will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the JU may be assisted by external persons or bodies.

The JU may also request additional information in accordance with Article 17. The JU may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The JU may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The JU may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The JU may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For on-the-spot reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The JU will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The JU or the Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started up to two years after the payment of the balance. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The JU or the Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The JU or the Commission may request beneficiaries to provide such information to it directly.

For on-the-spot audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a 'draft audit report' will be drawn up. The JU or the Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('contradictory audit procedure').

This period may be extended by the JU or the Commission in justified cases.

The 'final audit report' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The JU or the Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/201316 and No 2185/9617 (and in accordance with their provisions and procedures), and Article 50 of the JU Financial Rules18, the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and Article 50 of the JU Financial Rules, the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations
Not applicable

22.5 Consequences of findings in checks, reviews, audits and investigations — Extension of Findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other JU, EU or Euratom grants awarded under similar conditions ('extension of findings from this grant to other grants').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The JU or the Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other JU, EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The JU or the Commission will formally notify the beneficiary concerned the systemic or recurrent errors and its intention to extend these audit findings, together with the list of grants affected.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the JU or the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable

or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the JU or the Commission in justified cases.

The JU or the Commission may then start a rejection procedure in accordance with Article 42, on the basis of:

- the revised financial statements, if approved;
- the proposed alternative correction method, if accepted

or

- the initially notified correction rate for extrapolation, if it does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements.

22.5.3.2 If the findings concern **substantial errors**, **irregularities or fraud** or **serious breach of obligations**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the JU or the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

The JU or the Commission may then start a reduction procedure in accordance with Article 43, on the basis of:
- the proposed alternative flat-rate, if accepted
or
- the initially notified flat-rate, if it does not receive any observations or does not accept the observations or the proposed alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The JU or the Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the EU programme.

Evaluations may be started during implementation of the action and up to five years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The JU or the Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the JU may apply the measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the JU without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation. The JU may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50). Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF JU FUNDING AND SUPPORT FROM JU MEMBERS

38.1 Communication activities by beneficiaries

38.1.1 Obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the JU (see Article 52).

38.1.2 Information on JU funding and support from JU members — Obligation and right to use the logos and the EU emblem

Unless the JU requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure, equipment and major results funded by the grant must:

(a) display the JU logo, the logo of EFPIA and
(b) display the EU emblem and
(c) include the following text:

For communication activities:
"This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 831458. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA".

For infrastructure, equipment and major results:

"This *[infrastructure][equipment][insert type of result]* is part of a project that has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 831458. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA".

When displayed together with another logo, the logos and the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the logos and the EU emblem without first obtaining approval from the JU, the Commission or the JU Members .

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the logos and the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding JU responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the JU is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the JU

38.2.1 Right to use beneficiaries' materials, documents or information

The JU may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other material, such as pictures or audio-visual material received from any beneficiary (including in electronic form). This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

If the JU's use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the JU not to use it (see Article 52). The right to use a beneficiary's materials, documents and information includes:
(a) **use for its own purposes** (in particular, making them available to persons working for the JU or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);
(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);
(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);
(d) translation;
(e) giving **access in response to individual requests** under Regulation No 1049/200125, without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;
(g) **archiving**, in line with applicable document-management rules, and
(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b), (c), (d) and (f) to third parties if needed for the communication and publicising activities of the JU.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned). Where applicable (and if provided by the beneficiaries), the JU will insert the following information:
"© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the Innovative Medicines Initiative 2 Joint Undertaking under conditions."

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43). Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the JU

The JU cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence. The JU cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence of implementing the Agreement.

46.2 Liability of the beneficiaries

Except in case of force majeure (see Article 51), the beneficiaries must compensate the JU for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

ATTACHMENT D

Special Conditions

[eg. Software Services]